

FEB 12 2001

K003571

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

A. Device Name

Proprietary Name

Serono For Use with Gonal-F 1200IU Multi-dose Only at 600IU/ml Syringe
(herein after referred to as Serono Gonal-F 1200IU Syringe)

Classification Name

Syringe, piston (FMF)
21 CFR, Section 880.5860, Piston Syringe

These syringes come with a fixed:

Hypodermic single lumen needle
21CFR, Section 880.5570, Hypodermic Single Lumen Needle

Classification: Class II

Common Name

Piston syringe with a fixed hypodermic single lumen needle

B. Intended Use

The Serono For Use with Gonal-F 1200IU Multi-dose only at 600IU/ml is intended for manual aspiration of Gonal-F 1200 IU multi-dose only at 600 IU/ml and for the injection of this solution into body parts below the surface of the skin. The syringe is designed for manual use. It is specifically indicated for the Gonal-F 1200 IU solution manufactured by Serono Lab.

C. Device Description

The Serono Gonal-F 1200IU Syringe is comprised of a standard piston syringe with a permanently attached (fixed) hypodermic single lumen needle designed for the manual aspiration and injection of Gonal-F 1200 IU Multidose. The needle is covered by a protective cap. The graduated scale is specifically designed for Gonal-F 1200 IU Multidose at 600 IU/ml. This syringe is a 1cc/ml syringe with 27g x ½" needle.

D. Substantial Equivalence

The Serono Gonal-F 1200IU Syringe submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the cleared the Terumo Allergy Syringe (K908796).

E. Principle of Operation and Technology

The Serono Gonal-F 1200IU Syringe and the Terumo Allergy Syringe (K980796) are both operated manually.

F. Materials

The Serono Gonal-F 1200IU Syringe uses the same materials as the Terumo Allergy Syringe (K980796). There are no new issues of safety and effectiveness.

G. Specifications

Needle		Graduated Capacity
Gauge	Length	
27	½"	600 IU/1ml

H. Performance

- The Serono Gonal-F syringe will be tested for Barrel Volume (Graduated Capacity) in accordance with ISO 8537 and will comply with this standard prior to product release into distribution.

A risk analysis was conducted and there were no new issues of safety and effectiveness.

The performance of the Serono Gonal-F 1200IU Syringe is substantially equivalent to the performance of the Terumo Allergy Syringe (K980796).

I. Additional Safety Information

Manufacturing controls include visual, functional, and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137-1994 Medical Devices – Validation and Routine Control of Radiation Sterilization. The Serono Gonal-F 1200IU Syringe is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6} .

The Serono Gonal-F 1200IU Syringe is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Testing has been completed on the blood contacting materials of this syringe and all were found to be biocompatible.

Expiration dating for the Serono Gonal-F 1200IU Syringe will be 60 months.

J. Conclusion

The Serono Gonal-F 1200IU Syringe is substantially equivalent in intended use, design, technology / principles of operation, materials and performance to the Terumo Allergy Syringe (K980796). Differences between the devices do not raise any significant issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Ms. Barbara Smith
Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K003571
Trade Name: Serono For Use with Gonol-F 1200IU
Multi-dose Only at 600IU/ml Syringe
Regulatory Class: II and II
Product Code: FMF and FMI
Dated: November 17, 2000
Received: November 20, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

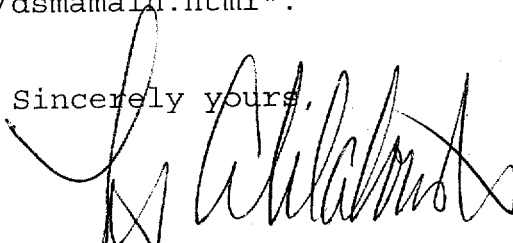
Page 2 - Ms. Smith

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003571

Device Name: Serono For Use with Gonal-F 1200IU Multi-dose only at 600IU/ml

Indications For Use:

The Serono For Use with Gonal-F 1200IU Multi-dose only at 600IU/ml is intended for manual aspiration of Gonal-F 1200 IU multi-dose only at 600 IU/ml and for the injection of this solution into body parts below the surface of the skin. The syringe is designed for manual use. It is specifically indicated for the Gonal-F 1200 IU solution manufactured by Serono Lab.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Patricia Cuccinelli
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003571